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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,960

05/09/2005

Bill Clark

PN0222

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36335

7590

11/19/2009

GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

KILPATRICK, BRYAN T

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

11/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,960	Applicant(s) CLARK ET AL.	
	Examiner BRYAN T. KILPATRICK	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 9-24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-8, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 November 2009 has been entered.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Amendment

1. The amendments and arguments/remarks filed on 12 November 2009 have been entered and fully considered.
2. The request for continued examination filed on 12 November 2009 has been entered.

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3. In light of Applicant's amendment, the objection to instant claim 1 is withdrawn.
4. In light of Applicant's arguments/remarks, the previous double patenting rejection is withdrawn, and replaced with a new rejection.
5. Instant claims 2-5 and 9-10 have been previously cancelled, instant claims 11-24 and 26 have been previously withdrawn, and instant claim 1 has been amended.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed **terminal disclaimer** in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-8, 25, and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16 of copending Application No. 10/311,108.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and claims 13-16 of copending Application No. 10/311,108 recites a method of analysis for a biological system containing at least one NMR active nuclei that a.) hyperpolarizes the NMR active nuclei, b.) generates a pattern for the system or samples extracted from the system using NMR analysis, c.) subjects the system to a change by introducing a drug, d.) further hyperpolarizes the NMR active nuclei, e.) generates a pattern for the system or samples extracted after introducing the drug, and f.) compares the NMR patterns for systems to identify any changes in NMR patterns. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method of copending Application No. 10/311,108 for the purpose of observing the effects of a drug introduced into a biological system since this is recited in the claims of copending Application No. 10/311,108. Furthermore, copending Application No. 10/311,108 discloses in paragraphs [0013]-[0014] that the method employs DNP as a method of polarizing NMR active nuclei, which is recited in instant claim 1, as well as the use of the same NMR nuclei in a variation of the method of the instant claims in claims 4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6-8, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over W. O. 01/96895 (COOK et al.), and further in view of W. O. 00/40988 (ARDENKJAER-LARSEN et al.).

In regards to instant claim 1, COOK et al. recites a method of analysis for a biological system containing at least one NMR active nuclei that a.) hyperpolarizes the NMR active nuclei, b.) generates a pattern for the system or samples extracted from the system using NMR analysis, c.) subjects the system to a change by introducing a drug, d.) further hyperpolarizes the NMR active nuclei, e.) generates a pattern for the system or samples extracted after introducing the drug, and f.) compares the NMR patterns for systems to identify any changes in NMR patterns (claims 13-16). COOK et al. further discloses in paragraphs [0013]-[0014] that the method employs DNP as a method of polarizing NMR active nuclei, as well as the use of the same NMR nuclei in claim 4.

COOK et al. does not expressly disclose the use of with at least two probe compounds containing at least one of C¹³ and N¹⁵ NMR active nuclei and acting as substrates, inducers, or inhibitors of a protein. However, ARDENKJAER-LARSEN et al. discloses the use of oligonucleotide or polynucleotide probes enriched with hyperpolarized nuclei to target specific areas of biological samples for acquiring specific information (page 15, lines 21-30). ARDENKJAER-LARSEN et al. further discloses assays encompassing methods such as competition and binding assays that employs enzyme-substrate inhibitors or reactions, nuclease assays, etc. (page 7, lines 13-19). Since both COOK et al. and ARDENKJAER-LARSEN et al. recite methods of observing biological systems, it would have been obvious to one of ordinary skill in the art to

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modify the method of COOK et al. to employ the probes of ARDENKJAER-LARSEN et al. for the purpose of observing whether or not probes have bound to a biological sample (page 15, lines 21-30 of ARDENKJAER-LARSEN et al.) after the introduction of a drug (claims 13-16 of COOK et al.).

In regards to instant claim 6, COOK et al. recites a method of analysis for urine sample in claim 12.

In regards to instant claims 7-8, 25, and 27; ARDENKJAER-LARSEN et al. teaches that “biological species” is one that is present in living systems, or that is introduced into and is reactive with such systems in lines 8-9 of page 4. The prior art also teaches an assay method for analyzing biological macromolecules such as proteins, e.g., enzymes, receptors, DNA, RNA binding proteins, and carrier proteins (similar to cytochrome); oligonucleotides such as DNA and RNA probes; macrocyclic molecules such as cyclodextrin; carbohydrate macromolecules; and lipids (page 4, lines 10-13). The prior art further teaches assays encompassed by the disclosed method such as enzyme-substrate inhibitors, nuclease assays, etc. (page 7, lines 13-19).

Even though ARDENKJAER-LARSEN et al. does not explicitly disclose the compounds recited in instant claims 7-8, 25, and 27, the description of “biological species” taught by the prior art describes the compounds recited by the instant claims. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to use compounds as biological species for the purpose of observing physical or chemical changes as disclosed in lines 6-7 of page 4.

Response to Arguments

Applicant's arguments/remarks, see p. 8-10, filed 12 November 2009, with respect to the rejection(s) of claim(s) 1 under provisional nonstatutory obviousness-type double patenting, 35 USC § 102(b), and 35 USC § 103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference(s) – see previously stated rejections above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is (571)270-5553. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797

/B. T. K./
Examiner, Art Unit 1797